ISRCTN69085979 https://doi.org/10.1186/ISRCTN69085979

Effects of synbiotics in infants with atopic dermatitis

Submission date	Recruitment status
20/12/2005	No longer recruiting
Registration date	**Overall study status**
20/12/2005	Completed
Last Edited	**Condition category**
05/11/2010	Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym
Synbad

Study objectives
Pre- and probiotics are able to change the composition of the altered intestinal microbiota that is found in allergic patients, indicating beneficial effects of these nutritional components in the

prevention and treatment of allergic diseases. The addition of a patented symbiotic mixture of prebiotics and probiotics to a standard infant formula is assumed to improve the clinical symptoms of Atopic Eczema Dermatitis Syndrome (AEDS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Primary study design
Interventional

Study design
Multicentre, randomised, double blinded, placebo controlled, parallel group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Atopic Eczema Dermatitis Syndrome (AEDS)

Interventions
Infants will receive in a double-blind fashion either standard infant formula or infant formula with added synbiotica, for 12 weeks.

Analyses:
1. Scorad
2. Questionnaires on AEDS symptoms
3. Blood collection for safety, immunological and immunological parameters
4. Stool collection for faecal microbiota evaluation

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prebiotics, probiotics

Primary outcome(s)
Decrease in Scorad score after 12 weeks of treatment is more than 25% greater in the active group compared to the placebo group.

Key secondary outcome(s)
1. Immunological parameters
2. Faecal microbiota parameters
3. Quality of life of the parents and parental stress
4. Gastro-intestinal tract characteristics

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Infants, between 0 and 7 months of age
2. Fulfilling standard criteria for AEDS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 Years

Upper age limit
7 Months

Sex
All

Key exclusion criteria
1. Scorad score 15
2. Use of anti-histamines or systemic corticosteroids or anti-mycotic drugs
3. Skin disorder other than AEDS

Date of first enrolment
01/09/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Numico Research B.V.
Alkmaar
Netherlands
6700 CA

Sponsor information

Organisation
Numico Research B.V. (The Netherlands)

ROR
https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

Funder Name
Numico Research B.V. (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2010		Yes	No